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Excimer Laser Assisted Angioplasty for Critical Limb Ischemia: Results of the LACI Belgium Study

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Background. *The purpose of this study was to assess the safety and efficacy of translating into national practice methodology for infrainguinal excimer laser-assisted angioplasty, for the treatment of critical limb ischemia in poor surgical bypass candidates.*
Methods. *A prospective five centre Belgian registry enrolled 48 patients, who presented with 51 chronic critically ischemic limbs (Rutherford category 4, 5 or 6) and were poor candidates for bypass surgery. Treatment included crossing the occlusion or stenosis by conventional guidewire followed by excimer laser angioplasty with, or without, adjunctive balloon angioplasty or stenting. A step-by-step technique was used in cases where the guidewire could not pass the occluded site. The primary endpoint was limb salvage, at 6 months, of the treated limb.*
Results. *Initial treatment was successful in all 51 limbs. By 6 months there had been six deaths, six minor and four major amputations and further intervention was required in four patients. Among survivors, limb salvage rate at 6 month was 38/42 (90.5%), with freedom from critical limb ischemia in 86%.*
Conclusions. *This Belgian study of eximer laser assisted angioplasty, in high-risk patients who were poor candidates for surgical re-vascularisation, had a low incidence of surgical re-interventions and limb salvage rate in excess of 90%.*

Keywords: Critical limb ischemia; Excimer laser; Revascularisation; Limb salvage; Infrapopliteal.

Introduction

Two decades after the clinical introduction of balloon angioplasty (PTA) as a recanalization technique in the femoropopliteal and infrageniculate arteries, a number of factors affecting the primary and long-term success of the procedure have been identified.[1–4] Short lesion length, minimal vascular disease elsewhere with good peripheral run-off, symptoms of claudication as opposed to limb-threatening ischemia, stenosis rather than occlusion, and the absence of diabetes all correlate with improved primary success and long-term patency.[5–17] For patients with critical limb ischemia (CLI), treatment options remain limited to medical management, bypass surgery or amputation. Those too fragile or unwilling to undergo the morbidity and mortality associated with bypass surgery are left to live with their pain or lose a lower limb.

Using PTA alone in the treatment of long below-the-knee occlusions has resulted in disappointing patency rates, although immediate clinical improvement has been achieved.[2,5,6] With advances in interventional tools, e.g. the excimer laser and coated/nitinol stents, and with the adoption of coronary interventional techniques in peripheral arteries, there are new possibilities for effectively treating total occlusions and diffuse disease below the knee.[18,19] Excimer lasing re-opens and enlarges the lumen and smoothens the lumen wall, enhancing the angiographic result of adjunctive PTA.[20–22] Results of recent clinical studies have associated these effects of excimer lasing with clinical outcomes;[22–24] this raises the question of whether such promising results can be sustained in routine clinical practice.

LACI Belgium

Given the promising results of laser angioplasty in critical limb ischemia (LACI),[23,24] we studied the

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translation of this methodology to additional sites in Belgium. The purpose of this study was to provide confirmatory evidence of the safety and efficacy of the LACI treatment strategy as specifically practised in Belgium.

Materials

This study was a prospective consecutive multicentre clinical registry at five sites in Belgium (Table 1). Patients were eligible for study inclusion if there was objective evidence of chronic critical limb ischemia (rest pain or non-healing ulcerative lesions or gangrene) with lesions in the superficial femoral, popliteal and/or infrapopliteal arteries. Written patient consent was required prior to patient enrolment. Local ethics committee approval was received prior to study initiation. This study was conducted in accordance with the Declaration of Helsinki.

Between January 7, 2003 and June 6, 2003, 48 patients were enrolled. LACI Belgium included patients with CLI (Rutherford Category 4–6) who had at least one angiographically identifiable infrageniculate target artery and who were poor surgical candidates. A poor surgical candidate was identified when any one of the following criteria was met: absence of venous autologous grafts; absence of or poor distal vessels for graft anastomosis; high risk surgical mortality evidence by ASA Physical Class 4 or higher. Treatment consisted of excimer laser angioplasty + PTA + optional stent, with the primary endpoints being limb salvage, wound healing, straight-line flow until the foot and total survival at 6 months.

Exclusion criteria were age below 18 years; pregnancy, or plan to become pregnant; participation in another cardiovascular or peripheral vascular IDE study; myocardial infarction (MI) in prior month; disorder or allergies precluding use of radiographic contrast; renal insufficiency severe enough to contraindicate use of radiographic contrast, contraindication to treatment with anticoagulants; untreated ipsilateral iliac stenosis > 70%; inability or unwillingness of the patient to comply with intended examinations; lesions located in a graft; hemodynamically significant arrhythmia or left ventricular ejection fraction < 20%; life expectancy less than 6 months; necrosis necessitating major amputation; or unavailability of required procedural or imaging equipment.

Table 1. Investigators LACI Belgium

Site name	Investigator	Leg	Pt
Imelda Ziekenhuis, Bonheiden	Dr Peeters	15	13
A.Z. Sint-Blasius, Dendermonde	Dr Bosiers	14	13
U.Z. Gent, Gent	Prof Vermassen	3	3
Hôpital Saint-Jozef, Gilly	Dr Massin	1	1
U.Z. Leuven-Gasthuisberg, Leuven	Dr Maleux	10	10
Sint-Trudo Ziekenhuis, Sint-Truiden	Dr Van Elst	8	8
	Total	51	48

The primary endpoint of this study was limb salvage (absence of major amputation, defined as an amputation of the treated limb at or above the ankle) at 6 months, on a per-limb basis. The secondary endpoints were: 'Peripheral vascular endpoint,' defined as major amputation or persistent CLI at 6 months (basis: limb); death during the follow-up period (basis: patient); incidence of minor amputation (basis: limb); persistent CLI (basis: limb); visual assessment of the healing process of ulcers (basis: ulcer); surgical bypass in the leg (basis: limb); surgical bypass to a previously unavailable site (basis: limb); reduction in degree of planned lower extremity amputation (basis: limb); angiographic procedural success rate (basis: limb) with angiographic procedural success defined as 50% or less residual stenosis on visual assessment of the planned area of treatment after completion of treatment, without serious adverse events and before the arterial sheath was removed. Data management was performed by Flanders Medical Research Program, Hamme.

Methods

Using standard intravascular techniques, a guidewire crossed the entire occlusion and entered the distal vessel beyond the target lesion. If free movement of the wire tip within the distal vessel was not observed, the wire was withdrawn and redirected. As an alternative method of recanalization, laser ablation was used in a step-by-step manner where the guidewire and then a laser catheter are sequentially advanced and activated in telescoping fashion until the occlusion was crossed. This step-by-step technique was used in 16% of the treated limbs.

After the wire crossed the target lesion, the lesion was treated with excimer laser atherectomy, unless satisfactory debulking had already been achieved through use of the step-by-step approach. Laser catheter sizes between 0.9 m and 2.5 mm were allowed (CLiRpath catheters, Spectranetics, Colorado Springs, Colorado, USA). It was recommended that as much tissue as possible was removed to achieve an optimal laser channel (at least 30–50% of vessel diameter). To

optimise the atherectomy, the laser catheter tip was advanced at a speed of approximately 0.5–1 mm/s while lasing and infusing saline through the guide catheter. After the laser catheter crossed the occlusion an angiogram was undertaken to assess the laser channel. Additional passes were made to improve the initial laser result at the discretion of the investigator.

Following laser use, PTA was delivered according to local standards. If an unsatisfactory result or a flow-limiting dissection ensued, stent implantation was used to achieve a widely patent lumen. Treatment typically advanced from the pelvic arteries to the tibial/pedal arteries until 'straight line flow' through at least one tibial artery was achieved from the groin to the foot. Anticoagulation was administered according to local standards, typically including aspirin, heparin, clopidogrel, and occasional use of Gp IIb/IIIa antagonists.

Results

A total of 48 patients (32 men), with 51 critically ischemic limbs and a mean age of 74.6 years (range 38–94) were enrolled. There was a high incidence of co-morbidities (Table 2). The actual outer diameter of laser catheters used and treated lesion locations are given in Table 3.

An antegrade approach was used in 84% of the patients to achieve good back-up support and alignment of the laser catheter. In 16% of the patients a contra-lateral approach (crossover) was used, with adequate back-up support at the iliac bifurcation to ensure appropriate device control at the treatment site.

Additional balloon dilatation was required in 33% of the patients to optimize the angiographic result; 6% of the patients had direct stenting after laser angioplasty; 47% required adjunctive PTA in combination with stent placement. In 14% of the patients excimer laser atherectomy was performed as a stand-alone procedure. All reported data and results were obtained by one of the treatments listed above. The study was not intended or powered to show statistical differences between the used treatment and/or a combination of the treatments (Table 4).

After 6 months, a limb salvage rate of 90.5% was obtained (38 out of the 42 surviving patients at 6 month follow-up (Table 5). During the 6-month follow period six patients died, five due to cardiac disease and one due to general systemic deterioration. Minor amputation, defined as an amputation of the distal or the mid-foot, leaving the patient with an ambulatory foot, was required in six patients throughout the follow up period. Four patients needed a major amputation, defined as amputation at or above the ankle. Surgical intervention was needed in two patients, and two patients received endovascular re-intervention. Freedom from any of these adverse events was observed in 76% of surviving patients at the end of the 6-month follow up period.

Rutherford classification improved as demonstrated in Graph 1. Of the 35 surviving legs with 6-month data, 30 (86%) were free of CLI.

Table 2. LACI Belgium patient and limb characteristics

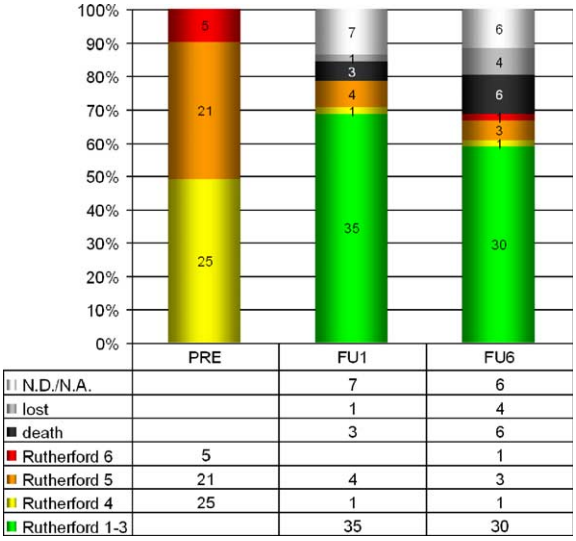
History of coronary artery disease (CAD)	29	57%
History of MI	12	24%
History of CABG	9	18%
History of PTCA	4	8%
Familial history of CAD	4	8%
Other	10	20%
History of stroke or CVA	14	27%
History of hypertension	38	75%
History of diabetes	24	47%
Diet controlled	2	4%
Oral hypoglycemics	7	14%
Insulin dependent	15	29%
History of hypercholesterolemia	25	49%
History of obesity	16	31%
Smoking past	12	24%
Smoking current	10	20%
History of CLI in treatment limb (N=51)		
History of CLI	48	94%
Rest pain	38	75%
Non-healing ulcerative wounds	24	47%
Gangrene	3	6%
Planned amputation	1	2%
Poor surgical candidacy (N=51)		
Absence of venous autologous graft	12	24%
Poor or no distal vessel	25	49%
High risk of surgical mortality (ASA class 4 or higher)	30	59%
Any two reasons	11	22%
All three reasons	5	10%
Rutherford category (N=51)		
Category 4	25	49%
Category 5	21	41%
Category 6	5	10%

Table 3. Laser catheter size and lesion locations

Laser catheter size distribution		
OD laser catheter tip		Number of catheters
0.9 mm		6
1.4 mm		9
1.7 mm		5
2.0 mm		13
2.3 mm		15
2.6 mm		15
Mean laser pulses delivered (no data in 12 patients)		3430 (900–11,100)
Average lasing time		134 (18–1200) s
Treated lesions		
Femoro-popliteal	21	41%
Infra-popliteal	16	31%
Combined	14	27%

Table 4. Adjunctive therapy used

Lasing	7	14%
Lasing and PTA	17	33%
Lasing and stenting	3	6%
Lasing, PTA and stenting	24	47%
Balloon information		
Mean number of PTA balloons used	1.24	63
Mean balloon diameter	4.06	(2–6)
Stent information		
Mean number of stents used	1.02	52
Mean stent diameter	5.60	(3–8)
Mean stent length	46.55	(40–100)



Graph 1. Evolution in Rutherford categorisation after 1, 3 and 6 months ($N=51$). N.A., not available. No information because the referred patients were lost to follow-up; N.D., not done. No information because no Rutherford evaluation was done at this follow-up visit.

Discussion

The basic concept of laser atherectomy is to apply light energy directly to the arterial plaque, thereby altering the plaque in a beneficial manner, without damaging the surrounding artery. Lasers suitable for intravascular use produce an intense monochromatic light beam that can be delivered through fiberoptic catheters to a small area of tissue with great precision. There are three parameters that define the laser/tissue interaction: absorption depth, pulse width and average power. Absorption depth can be defined as how deep the light propagates into the tissue. For precise work, this penetration depth must be as small as possible, to ensure that effects are localized to the point where the beam is applied and is determined only by the wavelength and the tissue. Each laser type emits a characteristic wavelength that is determined by the gain medium inside the laser. Selecting a particular wavelength to use in vascular tissue is fairly straightforward, once the typical absorption spectrum of tissue is plotted. In the near-infrared regions, between 2000 and 3000 nm, water is the dominant absorber; the light penetration depth varies from about 1 to 0.1 mm over this region. At the other end of the spectrum, in the UVB region near 300 nm, the absorption depth is shallow, owing to absorption by cellular macromolecules. Another advantage of using UVB light lies in its ability to break molecular bonds directly, by a photochemical process. Delicate measurements in tissue indicate that about 2% of the UVB photons absorbed by the proteins and lipids in cells actually breaks bonds, which weakens or lyses cellular structures. This direct lytic action is a unique feature of using ultraviolet light. The second parameter in light/tissue interaction is pulse width. For all lasers, most of the light energy absorbed by the tissue is converted to heat almost instantly. The third parameter of light/tissue interaction is average power. Ideally, the absolute minimum of heat would be deposited in the artery, since the typical response of arterial wall to thermal injury includes proliferative healing and restenosis. The minimum pulse energy for a pulsed laser system is determined by the penetration depth of the light and by the need to form a steam bubble on each shot; effectively, this creates a unique threshold energy density for each laser type.

Medical lasers have been evaluated for the

Table 5. Overall LACI Belgium results

	Discharge	Follow-up 1 month	Follow-up 6 months
N	51	46	51
Death	0	3	6
Lost to follow-up	0	1	3
Major amputation	0	0	4
Limb salvage (patients with freedom of death, not lost to follow-up)	51/51 (100%)	42/42 (100%)	38/42 (90%)
Limb salvage by intend-to-treat analysis	–	–	38/51 (74%)
Minor amputation	0	3	2
Surgical repair	0	1	2
Endovascular repair	0	0	2
Freedom of any procedure	51/51 (100%)	38/42 (90%)	32/42 (76%)

treatment of the most complex peripheral disease since the mid-1980s. Early clinical applications of laser angioplasty in severe atherosclerotic stenoses and occlusions utilized continuous-wave (CW), hot-tipped lasers, such as the Argon or the Nd:YAG lasers. In contrast to the pulsed 308 nm excimer laser, continuous wave laser systems constantly convert light energy into thermal energy which diffuses into and injures the surrounding tissue. Total thermal energy is transferred to the metal cap at the end of the probe resulting in temperatures in excess of 450 °C. Also, after the first laser shot, the catheter probe becomes covered by a layer of carbonized blood. The problem is compounded in Argon lasers that employ a wavelength that is actively absorbed by hemoglobin. This layer of carbonized blood absorbs the laser energy and prevents direct laser tissue interaction. Tissue ablation is achieved by a denaturation of the tissue followed by carbonization and vaporization. CW lasers also failed to ablate or penetrate calcified plaques. Despite a high technical success rate, these early experiments with thermal, continuous wave lasers resulted in significant complications such as aneurysm formation, late perforations and a high restenosis rate. As a result, continuous wave laser systems have been abandoned for arterial applications.

Pulsed XeCl excimer laser angioplasty of the leg arteries has been practised commercially in Europe since 1994. Unlike continuous wave lasers, the excimer laser makes optimal use of absorption depth, pulse width and average power. In terms of absorption depth, the excimer laser is to be placed in the UVB region of the spectrum near 300 nm, where the absorption depth is shallow, owing to absorption by cellular macromolecules. At 308 nm, where the XeCl laser emits, the typical absorption depth is about 0.05 mm (50 μm) and each photon of 308 nm light carries enough energy to break a single carbon–carbon bond. XeCl laser catheters remove a layer of about 10 μm thick with each pulse. Initially, photochemical bond breaking weakens cellular structures, and later cells explode when their internal water turns into steam. This leaves sub-cellular debris, and a shallow crater under the catheter. The debris washes downstream without embolizing distal capillaries, and the catheter tip advances into the crater. On the next laser pulse, the process repeats, allowing the catheter tip to nibble through the tissue, as each laser pulse removes a thin layer of tissue at the bottom of the crater. As all lasers convert the light energy absorbed by the tissue immediately to heat, the thermal effect in the irradiated tissue has to be confined in order to use pulsed lasers, such as the XeCl excimer laser successfully. Therefore, the laser pulse must deliver its energy in a time span much shorter than it takes for the heat to diffuse away from the tip of the catheter. Once thermal confinement is assured, tissue ablation can be achieved by forcing the tissue to absorb enough energy in one pulse to vaporize the most volatile liquid in the cells-water. This is accomplished by transmitting sufficient energy per pulse, through each fiber in the catheter, to ensure that the water content of the tissue in the thermal confinement zone under each fiber vaporizes. When looking at the average power, the threshold energy density for XeCl lasers is about 35 mJ of energy per square millimeter (mJ/mm^2) of optical fiber in the catheter tip. A typical 2 mm diameter excimer laser catheter has about .71 mm^2 of fiber and delivers 25 mJ of energy per pulse at the minimum fluence. Delivering significantly more energy than this creates a more violent reaction in the tissue (which can be advantageous in particularly tough or calcified lesions) but deposits greater heat in the process. In a nutshell, the 308 nm excimer laser utilises flexible fiber optic catheters to deliver intense bursts UV energy in short pulse durations. The advantages of UVB light are its short penetration depth of 50 μm and its ability to break molecular bonds directly, by a photochemical, rather than thermal, process similar to the widely used technique of excimer laser photorefractive keratectomy. (LASIK).

With the knowledge that medical lasers have matured and with the recent publications on excimer laser assisted angioplasty, we looked into the most recent data available. Previously, the LACI 2 study enrolled, CLI patients with the same inclusion and exclusion criteria as LACI Belgium.[24] At 15 sites in the

Table 6. LACI 2 patient and limb characteristics

145 Patients	
Mean age	72±10 (45–91)
Men	53%
Duration of CLI (weeks)	25±37 (1–261)
Risk factors	
Smoking	53%
Coronary artery disease	50%
Prior stroke	21%
Diabetes mellitus	66%
Hypertension	83%
Dyslipidemia	56%
Obesity	35%
155 Limbs	
Rutherford category	
4	29%
5 or 6	71%
Reasons for poor surgical candidacy	
Absence of venous graft	32%
Poor/no distal vessel	68%
High surgical risk	46%
Only one reason	61%
Any two reasons	33%
All three reasons	6%

US and Germany, LACI 2 enrolled 145 patients with 155 critically ischemic limbs and 423 lesions. Patient and limb characteristics were typical of patients with systemic vascular disease, but with a higher incidence of diabetes and non-healing ulcers (Rutherford category 5–6) than in LACI Belgium. LACI 2 patients presented with severe and diffuse vascular disease typical of critical limb ischemia (Table 6). In the 423 lesions, 41% were in the superficial femoral artery, 15% were in the popliteal artery and 41% were in infrapopliteal arteries. Further, 70% of the patients had a combination of stenoses and occlusions, making treatment very complex. In 26 cases, where step-by-step technique was used, procedure success ensued in 20 (77%), resulting in 6-month limb salvage in 21/23 (91%) of survivors. Serious adverse events in this subset were not significantly different from the rest of LACI 2 cases, indicating that step-by-step technique adds little additional risk to this patient group while substantially increasing the chances for success in total occlusions. In-hospital serious adverse events were infrequent in this very fragile patient group. There were no deaths, perforations with surgical repair or bypasses as a result of the procedure and no patient had acute limb ischemia post intervention. Serious adverse events during the 6-month enrolment period included 10% mortality, almost exclusively from cardiac causes. Major amputation was required in 11 cases, while four limbs received surgical intervention. Endovascular reinterventions were performed in 24 cases, as could be expected given the complexity of the disease. However, of surviving legs, 69% improved in Rutherford category, 27% maintained the same Rutherford category and only 4% declined. At 6 months, limb salvage was achieved in 93% of the surviving legs. Overall the results of LACI 2[24] and LACI Belgium show a remarkably similar record of success in a similar patient population. This finding supports the ability to translate an effective but somewhat complex endovascular strategy from international centres of excellence to selected centres within a national framework of healthcare standards (Table 7).

Table 7. LACI 2 results

Procedure results			
Guidewire crossing success	92%		
Laser treatment delivered	99%		
Adjunctive balloon	96%		
Stent placement	45%		
Procedure success	85%		
<50% residual stenosis at final			
Straight-line flow established	89%		
Mean hospital stay (days)	3		
Adjudicated SAEs			
	In-hospital	All follow-up	Total
Death	0	15	15
Major amputation	2	9	11
Non-fatal MI or Stroke	0	2	2
Reintervention	1	23	24
Hematoma w/surgery	1	0	1
Acute limb ischemia	0	1	1
Perforation w/surgery	0	0	0
Bypass	0	3	3
Endarterectomy	0	1	1
48 (33%) of patients experienced at least 1 SAE			

Conclusions

For patients with CLI, preserved mobility and quality of life should be the main factors in deciding on leg salvage attempts vis-à-vis primary amputation. The 6-month results of the LACI Belgium study confirm the excellent limb salvage rates in the selected patient population, seen previously in the LACI 2 study.[24] It is mandatory to emphasise that these patients were screened and selected as poor surgical candidates and presented with complex vascular disease that typically disqualifies them from bypass surgery. By using a single treatment strategy, and taking account of the early excimer laser experience of all participating centres, nearly all surviving patients retained their limbs, with clinically significant improvement in Rutherford category and a low incidence of complications.

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